## **REMARKS/ARGUMENTS**

The final office action of December 8, 2003 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested in view of the amendments and remarks presented in this response.

Applicants' representative wishes to thank the Examiner for his time during the Examiner's interview on February 23, 2004, during which all of the pending claims were discussed. Although no agreement on allowable subject matter was reached, the undersigned gained a better understanding of the Examiner's position. During the interview, Applicants' representative and the Examiner discussed possible amendments to independent claims 1 and 14 that would better point out the claimed invention in view of the cited references, including Unger (U.S. Patent No. 6,416,740) and Gordon (U.S. Patent No. 4,735,796). Possible amendments to the composition claims that were discussed included limitations relating to the composition and size of the microsphere shells and the particles contained within the walls of the microsphere shells. Applicants' representative and the Examiner also discussed the ability to use a single dose of the compositions to obtain two images from two different imaging modalities. In this regard, Applicants' representative and the Examiner discussed possibly amending claim 14 (method) to incorporate the subject matter of dependent claims 15, 17 and 18. The various amendments discussed are reflected in the amended claims herein.

Claims 1, 4, 6, 14 and 23-36 remain pending in this application. Claims 1, 4, 6 and 14 have been amended. Claims 2, 3, 5, 7, 8, 15 and 17-22 have been canceled. Claims 1 and 14 are the remaining independent claims. Dependent claims 23-34 have been added. Support for these

amendments can be found throughout the specification, and no new matter has been introduced.

Claims 9-13 and 16 have been previously withdrawn from consideration.

## REJECTIONS UNDER 35 U.S.C. §102

Claims 1, 2, 5, 7, 8, 14, 15, 17, 18, 19, and 22 stand rejected under 35 U.S.C. §102(e) as anticipated by Unger (U.S. Patent No. 6,416,740). Applicants have canceled claims 2, 5, 7, 8, 15, 17-19 and 22, rendering this rejection moot with respect to these claims. Reconsideration and withdrawal of this rejection is respectfully requested.

Pending claims 1, 4, and 6 as presently amended and new claims 23-29 are directed to an imaging composition that is effective in a single dose and includes one or more particles including gadolinium oxide and one or more microsphere shells including a protein comprising albumin. The microsphere shells have an average diameter of no more than about 70,000 Å. Dependent claims 4, 6, and 23-28 recite further limitations relating to the size and characteristics of the microsphere shells and the particles encapsulated between the walls of the shells. More specifically, claim 4 recites that the particles are speherical. Claims 6 and 23-25 recite that the particles have diameters of no more than 450 Å, between about 50 Å and about 20,000 Å, between about 50 Å and about 750 Å, and about 200 Å to about 400 Å, respectively. Claim 26 recites that the microsphere shells have an average diameter of between about 5,000 Å and about 40,000 Å. Claims 27 and 28 recite that the particles are pegylated and have diameters between about 200 Å to about 400 Å, respectively. Claim 29 recites that the albumin is selected from the group consisting of bovine serum albumin, human serum albumin and combinations thereof.

Claim 14 as presently amended and new claims 30-36 are directed to a method of obtaining images using two or more medical diagnostic imaging modalities using an imaging

composition that includes a suspension of microsphere shells including a protein comprising

albumin, the walls of the shells encapsulating particles including gadolinium oxide. Dependent

claims 30-36 recite further limitations relating to the size and characteristics of the microsphere

shells and the particles encapsulated between the walls of the shells. More specifically, claims

30-32 recite that the particles have diameters between about 50 Å and about 20,000 Å, between

about 50 Å and about 750 Å, and about 200 Å to about 400 Å, respectively. Claim 33 recites

that the microsphere shells have an average diameter of between about 5,000 Å and about 40,000

Å. Claims 34 and 35 recite that the particles are pegylated and have diameters between about

200 Å to about 400 Å, respectively. Claim 36 recites that the albumin is selected from the group

consisting of bovine serum albumin, human serum albumin and combinations thereof.

Unger does not teach or disclose an imaging composition that includes one or more

particles including gadolinium oxide and one or more microsphere shells having an average

diameter of no more than about 70,000 Å and including a protein including albumin. Unger

further does not teach or disclose administration of such a composition in a single dose to obtain

two or more images from different modalities without administration of an additional amount of

the imaging composition or an amount of another imaging composition to obtain the second

image. Unger also does not disclose microsphere shells with particles including gadolinium

oxide, where the particles are pegylated. Thus, Unger does not teach each element of the

claimed invention as required under 35 U.S.C. §102(b). Reconsideration and withdrawal of the

rejection are respectfully requested.

Page 8 of 10

## REJECTIONS UNDER 35 U.S.C. §103

Claims 1-8, 14, 15 and 17-22 stand rejected under 35 U.S.C. §103 as being unpatentable over Unger (U.S. Patent No. 6,416,740) in view of Gordon (U.S. Patent No. 4,735,796). Applicants have canceled claims 2-3, 5, 7, 8, 15 and 17-22, rendering this rejection moot with respect to these claims. Reconsideration and withdrawal of this rejection is respectfully requested.

As discussed above, Unger does not disclose, teach or suggest the present imaging compositions or methods of using such compositions to obtain multiple images from medical diagnostic imaging modalities. Gordon does not provide any teachings for curing the deficiencies of Unger. Gordon teaches ferromagnetic, diamagnetic and paramagnetic particles in the treatment of cancer cells, as well as correlation of the magnetic characteristics of the particles with intracellular temperature of the cancer cells for diagnostic purposes. Gordon does not disclose, teach or suggest imaging compositions that include gadolinium oxide particles encapsulated in albumin microsphere shells having average diameters of no more than about 70,000 Å for use in a single dose. Gordon further does not disclose, teach or suggest administration of such a composition in a single dose to obtain two or more images from different modalities without administration of an additional amount of the imaging composition or an amount of another imaging composition to obtain the second image. Thus, Gordon does not teach or suggest the claimed invention.

Therefore, neither of the cited references, whether taken alone or in combination, disclose, teach or even suggest the present imaging compositions or methods of obtaining images

Appln. No.: 09/976,746

Amendment dated March 8, 2004

Reply to Office Action of December 8, 2003

using such compositions, and the present claims are not obvious. Reconsideration and

withdrawal of the rejection are respectfully requested.

**CONCLUSION** 

It is believed that no fee is required for this submission. If any fees are required or if an

overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No.

19-0733, accordingly.

All rejections having been addressed, applicant respectfully submits that the instant

application is in condition for allowance, and respectfully solicits prompt notification of the

same.

The Examiner is invited to contact the undersigned if necessary to facilitate prosecution

of this application.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: March 8, 2004

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